August 4, 1999

Documents Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane #1061
Rockville, MD 20852

As a laboratorian, a taxpayer, and most importantly, a child of aging parents, I am writing this letter as personal communication to voice my concerns regarding the HFA-305 draft document dealing with the HCV Lookback program. My understanding of the proposed Lookback is that (1) it will use a 1990 HCV test which has a high percentage rate of false positive test results, and (2) it will search historical records that are retrievable ad infinitum.

My concerns are "risk versus reward." The program would be costly, the benefits would be negligible and the emotional distress it could cause our elderly population (the age group most affected by the results of the Lookback) is frightening and unnecessary.

Please consider a proactive versus a reactive approach to the Lookback! IDEA: As patients who where previously transfused present to a physician's office or hospital, test for HCV. And/or, possibly, include a test for HCV to the annual physical exam.

Thank you for you consideration of my concerns.

Peggy H. Dodson, MT (ASCP)

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